UMMS Human Research Protection Program (HRPP) Newsletter

Volume 2 October 19, 2015

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Visit us on the web:

http://www.umassmed.edu/ccts/human-research/

AAHRPP Boot Camps and Site Visit

The UMMS AAHRPP accreditation site visit took place September 1-3, 2015.

The site visit included a records review and interviews with selected investigators, study personnel, IRB members and key individuals within human research administration.

The site visitors remarked on the strength of our human research protection program and the dedication of investigators and study personnel in protecting human subjects, evident from interview sessions. Site visitors were impressed by the collaboration and teamwork demonstrated by study teams and throughout program.

AAHRPP's final decision will be issued mid-December. If successful, UMMS will receive a 3 year accreditation.

In order to prepare for the site visit, and as part of our HRPP Education program, we ran a successful series of *Boot Camps* over the summer months. We plan to offer encore sessions in the future.

Key points from the sessions are highlighted below. Even though our site visit is over, these are important points to consider ***every day*** as we work to protect the subjects who participate in our studies.

Boot Camp Highlights

Session 1: Human Research, Resources & Feasibility

♦ Activities that involve both *research* and *human subjects* require IRB approval. Refer to HRP-421: Human Research or *contact the IRB* if you aren't sure whether you need approval.

♦ Bookmark HRP-800: Investigator Obligations. Know it and refer back to it often!

♦ Feasibility means making sure you have enough ***staff, time, training and resources*** to conduct a study. This helps to protect subject safety and gives you the best chance of successfully completing your study.

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HRPP QUALITY CORNER: Spotlight on…

One goal of the HRPP QA/QI program is to review at least 10% of all active, non-exempt studies with an informed consent process. Terry Sousa, QA/QI Manager, conducts these reviews, reports summary findings on a quarterly basis to HRPP leadership, and provides a summary of findings to the Clinical Research Professionals Group (CRPG) at the end of each fiscal year. *Three key areas for improvement* in FY2015 included:

Informed Consent: 57% of audited consents were missing the IRB approval stamp and 14% of audited consents were dated for the subject by study personnel.

IRB Documentation: 53% of findings related to study personnel who were not IRB approved.

Regulatory Documentation: 25% of findings were related to missing licenses, CVs or proof of CITI training for study personnel.

Click HERE to read Terry's full auditing report.

Office of Clinical Research
Human Research
Protection Program
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Helpful Hints from the IRB

Submitting a Modification for an IRB-approved study?

Use the *Modification Summary* to tell the IRB how many subjects are already enrolled, when and how subjects will be re-consented, or why re-consenting is not necessary.

eIRB Job-Aids can help you reduce common audit findings!

Job aids are now available on:

- How to print IRB-stamped consents
- How to edit/update study personnel in eIRB

**If you're having trouble with a specific action, the IRB is always available to help. First, please visit the Job Aids page to see if there is a Job Aid or video to assist you.*

(Boot Camp Highlights— continued from page 1)

Session II: Conflict of Interest

Investigators should be familiar with and know where to find the following documents (click on each link):

- HRP-120: Management of Financial Interest
- UMMS Procedure for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research
- University of Massachusetts Policy on Faculty Consulting and Outside Activities - Lowell and Worcester
- Committee on Oversight of Individual Conflicts of Interest in Research with Human Subjects

Session III: Informed Consent

- HRP-802: Informed Consent provides guidance about the generally suitable process to obtain informed consent.
- Seek IRB guidance & approval to consent special populations (cognitively impaired adults, children, non-English speaking subjects, and others).
- NEVER sign or date a consent form for a subject.
- If participation in a study might impact a subject's *clinical care*, be sure to place a copy of the informed consent form in the subject's medical record.

Session IV: PI Responsibilities, Oversight & Reportable New Information (RNI)

- You *must* report any unforeseen or unexpected incident that: adversely affects the rights, safety, or welfare of the subjects or others involved in the research; or suggests that the research places subjects or others at a greater risk of harm related to the research than was previously known or recognized.
- Be familiar with what constitutes Reportable New Information (RNI), and know that RNIs must be reported to IRB within 5 days (or sooner if especially serious), even if corrected/addressed.
- Know what constitutes a **Serious Adverse Event.**

Upcoming Education Opportunities

Clinical Research Professionals Group (CRPG) Meetings	**Webinars**	**Coordinator Training**
Monday, 10/19/15 12-1 PM Hiatt S1-608 Monday, 11/16/15 3-4 PM Hiatt S1-608 Wednesday, 12/16/15 12-1 PM Lazare S1-607	Join us as we broadcast an AAHRPP sponsored webinar on: **Vulnerable Populations** Tuesday, October 27 10:00– 11:30 AM webinar with discussion to follow. Location TBA Please RSVP **HERE**	**Intermediate level Clinical Research Coordinator training** * Coming in January! * Watch for announcement and registration link.